

Tilcosin Solution

For Veterinary Use Only

COMPOSITION:

Each ml contains:

Tilmicosin.....250mg

PHARMACOLOGY:

MECHANISM OF ACTION:

- Binds to 50S ribosome and inhibits protein synthesis and exhibits bacteriostatic activity
- Ribosome is cell organelle which takes part in protein synthesis, having two parts i.e. 50S and 30S
- Tilmicosin binds to 50S and inhibits translocation of t-RNA here, which is a vital step in protein synthesis
- 50S is found only in bacterial Ribosomes and not in that of animals. This fact confers selectivity to Tilmicosin Solution.

PHARMACOKINETICS:

Similar absorption through oral and parenteral route

CONTRAINDICATIONS/PRECAUTIONS/REPRODUCTIVE SAFETY:

Toxicity and side effects are uncommon for most macrolides (except Tilmicosin). Hypersensitivity reactions have occasionally been seen. Erythromycin estolate may be hepatotoxic and cause cholestasis; it may also induce vomiting and diarrhea, particularly when high doses are administered. Horses are sensitive to macrolide-induced GI disturbances that can be serious and even fatal. In pigs, Tilmicosin may cause edema of the rectal mucosa, mild anal protrusion with diarrhea, and anal erythema and pruritus. After 5 mg/kg/day, dogs had a greater tendency to develop ventricular tachycardia and fibrillation during acute myocardial ischemia. Tilmicosin is characterized by cardiac toxicity (tachycardia and decreased contractility). It is contraindicated in swine and should not be used in an extra-label manner. Cattle have died after IV injection of Tilmicosin.

INTERACTIONS:

Macrolide antibiotics probably should not be used with chloramphenicol or the lincosamides because they may compete for the same 50 S ribosomal binding site, although the in vivo significance of this potential interaction is unclear. Activity of macrolides is depressed in acidic environments. Macrolide preparations for parenteral administration are incompatible with many other pharmaceutical preparations. Erythromycin and troleandomycin are microsomal enzyme inhibitors that depress the metabolism of some drugs.

EFFECTS ON LABORATORY TESTS:

Alkaline phosphatase, bilirubin, sulfobromophthalein, total WBC count, eosinophil count, AST, and ALT may increase. Cholesterol levels may decrease.

TOXICOLOGY:

The cardiovascular system is the target of toxicity, and this toxicity may be due to calcium channel blockade. Administration of intravenous calcium chloride should only be considered if there is positive confirmation of exposure to Tilmicosin.

In dogs, tilmicosin induced a negative inotropic effect with consequent tachycardia and a reduction in systemic arterial blood pressure and arterial pulse pressure.

The LD₅₀ in Sheep after SC administration is > 150 mg/kg bw. While through IV it was > 7.5 (1/5 died) Ref: Cochrane & Thomson, 1990.

CARCINOGENICITY STUDIES:

Tilmicosin has not been tested in toxicological studies longer than 12 months in duration and hence the carcinogenic potential of this drug has not been directly determined. There are a number of observations which are relevant in assessing the carcinogenicity of Tilmicosin:

- a) The results of available toxicological studies with Tilmicosin have not identified lesions or proliferative changes which could be considered suggestive of potential neoplasia.
- b) Tilmicosin has been tested in a wide range of genotoxicity assays. All results were negative and it was concluded that the compound has no genotoxic activity.
- c) Tilmicosin is a macrolide antibiotic. This class of chemical has been in widespread usage in humans for many years but there is no evidence of carcinogenicity.

INDICATIONS:

It is indicated for the treatment and control of respiratory infection in chicken flocks, associated with *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, *Ornithobacterium rhinotracheale*, *Pasteurella multocida* and other organisms sensitive to tilmicosin.

DOSAGE AND ADMINISTRATION:

Administer the following dose orally via drinking water: 75mg Tilmicosin in 1 liter of water or 0.3 ml of Tilmicosin Solution in 1 liter of water for 3 days.

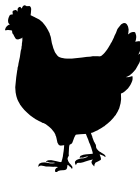
PRECAUTIONS:

1. Weight of the animal must be calculated accurately for proper medication.
2. This product is not for injection purpose.
3. Store between 15-25°C in a cool and dry place.

WITHDRAWAL TIME:

Chicken
Meat: 12 days.

Selmore's Specs.



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